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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,971	11/18/2003	Edward William Adams	7725-0001.02	7564

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EXAMINER

LE, HOA T

ART UNIT

PAPER NUMBER

1773

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,971

Applicant(s)

ADAMS ET AL.

Examiner

H. T. Le

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1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-189 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46-95 and 141-189 is/are allowed.
- 6) ☒ Claim(s) 1-45 and 96-140 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. Claims 1-45 and 96-140 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42-44 of U.S. Patent No. 6,649,138 ("the '138 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.
3. Although the preamble of claims 42 and 44 is a water-dispersible nanoparticle, the substance of the claim is directed to a product that comprises water-dispersible nanoparticle conjugated with an affinity molecule. This subject matter is essentially the "conjugate" recited in the instant claim 1. Features recited in claims 2-45 can be found in the specification of the '138 patent by definition or inherency.
4. Although the preamble of claim 43 is "water-dispersible nanoparticle", the substance of the claim is directed to: (1) a conjugate comprising water-dispersible nanoparticle conjugated with an affinity molecule as a first member of a binding pair and (2) the conjugate is associated with a second member of a binding pair. This subject matter is essentially the "nanoparticle conjugate" recited in the instant claim 96. Features recited claims 97-140 can be found in the specification of the '138 patent by definition or inherency.

Claim Rejections - 35 USC § 112

5. Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, the subject matter is inconsistent with that of claims 1 on which it depends. Claims 11-15 are deemed indefinite in view of their dependency on claim 10.

Allowable Subject Matter

6. Claims 46-95 and 141-189 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art references teach or suggest a conjugate of the nanoparticle and an affinity molecule, comprising the specific amphipathic polymer in an outer layer and an oxyalkylene linker binding the amphipathic polymer to a functional group as claimed. The most pertinent reference is the Bawendi patent (US 6,319,426). However, the Bawendi patent does not teach an oxyalkylene linker. In addition, the Bawendi patent does not teach a multiply amphipathic polymer according to the instant invention. The polymer taught by Bawendi does not contain at least two hydrophobic regions and at least two hydrophilic regions within the same polymer as required in the instant claims. Rather Bawendi teaches a molecule that contains one linker, one hydrophobic region that terminates with a hydrophilic group to provide water solubility to the particle. See col. 7, lines 10-15.

Response to Applicants' Remarks

8. Though deeply puzzled, the examiner sincerely regrets that her recitation of facts was perceived as an implication of irresponsibility on Applicant's Representative, especially when the failure to respond was due to the Representative's illness. The examiner simply explained why the previous office action contained just a minor rejection that could have been resolved with a quick phone call. The examiner's fact statement may not have been versed to deserve the Representative's approval, but it was not written out of "frustration", "irritation" or meant to "blame" as insinuated in the Representative's remarks. Honestly, upon re-reading it, the examiner still cannot see anything personal about what was written. In addition, the examiner notices that the office action was mailed on February 25, and the end of quarter (second quarter) was March 26, which was one month away from the mailing date. So it's quite bewildering to the examiner that Applicant's Representative mentioned "frustration" and "under pressure" during the "last days of the end of quarter".

The examiner would like to note with appreciation that an associate from the office of the Representative of record, Mr. Mark Warzel, contacted the examiner, as an alternative representative, trying to resolve the issues during the period when the Representative of record was unavailable (due to illness). However, nothing was accomplished because it was one day after the office action had been completed and sent to the supporting staff for mailing.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

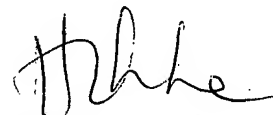
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the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



H. T. Le
Primary Examiner
Art Unit 1773